

REMARKS

Applicants have added new dependent claims 115-117. Claims 60, 61, 63-68, 70-72, 74-79, and 113-117 are pending.

As an initial matter, Applicants respectfully request the Examiner to **withdraw the finality of the Office Action** because it includes a new ground of rejection, which was not necessitated by any amendment or by any submission in an Information Disclosure Statement (IDS). See M.P.E.P. § 706.07(a). In particular, the finality of the outstanding Office Action should be withdrawn because the rejection of claims 113 and 114 under 35 U.S.C. § 102(b) based on newly-cited U.S. Patent No. 4,692,146 to Hilger (“Hilger”) is a **new ground of rejection which was not necessitated by an amendment**. Although claims 113 and 114 were amended in the Reply to Office Action filed on May 26, 2006 (“Reply”), these claim amendments merely placed each of claims 113 and 114 in independent form by adding language from a respective claim from which they previously depended. In other words, the previous amendment to claims 113 and 114 **did not change the scope of these claims** at all. Furthermore, Hilger is a reference newly cited by the Examiner in the Office Action, not a reference cited in a recent IDS. Thus, in accordance with M.P.E.P. § 706.07(a), which specifies that an Office Action should not be made final if it includes a new ground of rejection not necessitated by any amendment or submission in an IDS, the finality of the Office Action is improper and should be withdrawn.

According to M.P.E.P. § 706.07,

present practice does not sanction hasty and ill-considered final rejections. The applicant who is seeking to define his or her invention in claims that will give him or her the patent protection to which he or she is justly entitled should receive the cooperation of the examiner to that end, and

not be prematurely cut off in the prosecution of his or her application. . . .

The examiner should never lose sight of the fact that in every case the applicant is entitled to a full and fair hearing, and that a clear issue between applicant and examiner should be developed, if possible, before appeal.

To provide Applicants with a "full and fair" opportunity to respond to the final Office Action, Applicants respectfully request the Examiner to consider the above remarks and to withdraw the finality of the Office Action. If the Examiner refuses to grant this request to withdraw the finality of the Office Action, Applicants respectfully request the Examiner to explain the assertion at page 5 of the Office Action about how "Applicant's amendment necessitated the new ground(s) of rejection." Such an explanation would be especially appreciated so that Applicants will have more information to include in a possible petition to the Group Director requesting withdrawal of the finality of the Office Action.

The Section 102(e) Rejection Based on Villani Should Be Withdrawn

In the Office Action, claims 60, 61, 63-68, 70-72, 74-79, 113, and 114 were rejected under 35 U.S.C. § 102(e) based on U.S. Patent 5,848,989 to Villani ("Villani"). The Office Action at pages 2-3 asserts that Villani discloses an access port and cites reference numeral 6 of Villani for the asserted disclosure of an access site. In addition, the Office Action apparently cites reference numeral 13 of Villani for the asserted disclosure of a guidewire or stylet. Villani at 2.

Applicants respectfully submit that the Section 102(e) rejection should be withdrawn because Villani does not disclose the subject matter recited in independent claims 60, 70, 113, and 114.

Independent Claims 60 and 70 Are Allowable Over Villani

Villani fails to disclose an access port device including, among other features, an “access site” and an “entry site . . . , wherein the device is configured to permit access to [a] reservoir via the access site,” as recited in claims 60 and 70. Contrary to the assertion in the Office Action, reference numeral 6 of Villani does not constitute an access site. Reference numeral 6 of Villani refers to an enclosed, hollow body portion that receives a septum 4 and a hollow core 3. See Villani at col. 3, lines 32-33 and col. 4, lines 21-26. Villani does not disclose any configuration that permits access to a reservoir via the enclosed, hollow body portion 6, and thus the enclosed hollow body portion 6 does not correspond to the access site recited in claims 60 and 70.

The Office Action fails to provide any meaningful explanation of why the Examiner has equated Villani’s enclosed, hollow body portion 6 with the access site recited in claims 60 and 70. Although the Office Action at page 3 cites Figs. 2 and 3 of Villani, these drawing figures of Villani do not illustrate a configuration permitting access to a reservoir via the enclosed, hollow body portion 6. In particular, the assembled view of Fig. 3 shows both the septum 4 and the core 3 inserted into the enclosed, hollow body portion 6 without having any configuration that permits access to a reservoir via the portion 6.

Applicants respectfully disagree with the apparent assertion associated with the Examiner’s statement that “the access site also does not state what it necessarily gives access to.” Office Action at 3. Claims 60 and 70 specifically recite a configuration that “permit[s] access to a reservoir via the access site” and, thus, require the recited access

site to permit access to a reservoir. The claim recitation of a “device [that] is configured to permit access to [a] reservoir via an access site” is a positive structural limitation that must be given patentable weight. Nothing supports the Examiner’s labeling of this recitation as a “negative limitation” and, more importantly, even if it could be considered as a negative limitation (which it cannot), the limitation still must be given patentable weight.

For at least these reasons, claims 60 and 70 are allowable over Villani.

Independent Claims 113 and 114 Are Allowable Over Villani

Villani also does not disclose the system recited in claims 113 and 114, including, among other features, one of a guidewire and a stylet in combination with an access port device having a configuration that “permit[s] insertion of said one of a guidewire and a stylet through [a] body portion and into [an] outlet.” Contrary to the apparent assertion in the Office Action at page 2, reference numeral 13 of Villani refers to a needle, which is not necessarily the same as, and does not disclose, “one of a guidewire and a stylet,” as positively recited in claims 113 and 114. Moreover, even hypothetically if the needle 13 of Villani were to be considered as being one of a guidewire and a stylet, Villani does not disclose a configuration that would permit inserting the needle 13 “through [a] body portion and into [an] outlet,” as recited in claims 113 and 114. For example, Villani lacks any disclosure of a configuration that permits an end of needle 13 to pass through the outlet 9. Accordingly, Villani does not disclose the system recited in claims 113 and 114, and claims 113 and 114 are allowable over Villani.

Applicants note that the Office Action does not contain any response to Applicants' remarks included in the Reply filed May 26, 2006, explaining why the Section 102(e) rejection of claims 113 and 114 based on Villani is improper. See the Reply at page 10. If the Examiner maintains the rejection of these claims, Applicants would greatly appreciate a further explanation of the rejection and the Examiner's written comments responsive to Applicants' traversal of the rejection. See, e.g., M.P.E.P. § 707.07(f) (requiring an examiner to answer the substance of an applicant's arguments when repeating a rejection).

All of the Pending Claims Are Allowable Over Villani

For at least these reasons, independent claims 60, 70, 113, and 114 should be allowable over Villani. Claims 61, 63-65, 68, 71, 72, 74-79 and 115-117 depend from either claim 60 or claim 70 and, thus, those dependent claims should also be allowable.

The Section 102(b) Rejection Based on Hilger Should Be Withdrawn

In the Office Action, claims 60, 61, 63-65, 68, 70-72, 74-79, 113, and 114 were rejected under 35 U.S.C. § 102(b) based on Hilger.

Applicants respectfully submit that the Section 102(b) rejection based on Hilger should be withdrawn because Hilger does not disclose all of the features recited in independent claims 60, 70, 113, and 114.

Independent Claim 60 is Allowable Over Hilger

Hilger does not disclose an entry site "disposed opposite [an] outlet and being configured to permit insertion of one of a guidewire and a stylet through [a] body portion and into [an] outlet," as recited in claim 60. Contrary to the assertion in the Office Action at page 4, reference numeral 12 of Hilger does not correspond to the entry site recited

in claim 60. Reference numeral 12 of Hilger refers to a lumen. The lumen 12 is not “disposed opposite an outlet,” as recited in claim 60. Moreover, nothing supports the assertion in the Office Action at page 4, regarding the purported “shape and size and position” of the lumen 12 and the alleged “recogni[ti]on by persons of ordinary skill in the art.” Accordingly, Hilger lacks disclosure of an entry site “disposed opposite [an] outlet and being configured to permit insertion of one of a guidewire and a stylet through [a] body portion and into [an] outlet,” as recited in claim 60.

Claim 60 is also allowable over Hilger because Hilger does not disclose a device, including “an outlet configured to be in flow communication with [a] reservoir; an access site . . . ; and an entry site . . . configured to permit insertion of one of a guidewire and a stylet through the body portion and into the outlet, . . . wherein the device is configured to permit access to the reservoir via the access site,” as recited in claim 60. The Office Action at page 4 incorrectly equates reference numeral 37 of Hilger with the outlet recited in claim 60. Reference numeral 37 of Hilger is an opening in a boss 34 that receives a catheter 30. Hilger at Col. 3, lines 45-46. The opening 37 does not correspond to the outlet recited in claim 60 because the opening 37 is not “configured to be in flow communication with [a] reservoir,” as recited in claim 60. For example Figs. 4-6 clearly show the catheter 30 making contact with the entire inner surface of the opening 37, and thus preventing any fluid communication between the opening 37 and the cavity 23’, which the Examiner equates with the recited reservoir. Consequently, Hilger does not disclose “an outlet configured to be in flow communication with [a] reservoir” in combination with the other features recited in claim 60.

For at least these reasons, claim 60 is allowable over Hilger.

Independent Claim 70 is Allowable Over Hilger

Claim 70 recites a device including a reservoir, “an entry site . . . configured to permit access to the reservoir[,] . . . and an access site . . . configured to permit access to the reservoir.” In other words, claim 70 requires both an entry site and an access site to be configured to permit access to the same reservoir. Applicants respectfully submit that claim 70 is allowable over Hilger because Hilger does not disclose such configurations. For example, Hilger’s lumen 12, which the Examiner has attempted to equate with the recited entry site, doesn’t have a configuration permitting access to Hilger’s cavity 23’, which the Examiner has equated with the recited reservoir.

For at least these reasons, claim 70 is allowable over Hilger.

Independent Claims 113 and 114 Are Allowable Over Hilger

As mentioned above, each of claims 113 and 114 positively recites “one of a guidewire and a stylet” in combination with an access port device having a configuration that “permit[s] insertion of said one of a guidewire and a stylet through [a] body portion and into [an] outlet” Hilger does not disclose this combination of features. For example, Hilger does not mention or otherwise teach the recited “one of a guidewire and stylet,” as recited in claims 113 and 114. Consequently, claims 113 and 114 are allowable over Hilger.

If the Examiner insists on maintaining the rejection based on Hilger, Applicants would greatly appreciate a further explanation of how the claims are being rejected.

All of the Pending Claims Are Allowable Over Hilger

For at least these reasons, independent claims 60, 70, 113, and 114 should be allowable over Hilger. Claims 61, 63-68, 71, 72, 74-79 and 115-117 depend from either claim 60 or claim 70 and, thus, those dependent claims should also be allowable.

Conclusion: The Application is in Condition for Allowance

Applicants respectfully request that the Examiner reconsider the application, withdraw the finality of the previous Office Action and all of the claim rejections, allow all of the claims, and issue a Notice of Allowability in a timely manner.

The Office Action contains a number of statements relating to the claims of the present application and the cited references. Applicants decline to subscribe to any statement in the Office Action, regardless of whether it might be specifically mentioned above.

If a telephone conversation might advance prosecution of the present application, the Examiner is invited to contact the undersigned (571-203-2774).

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: November 15, 2006

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